

K960046

APR - 2 1996

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with CFR 807.92 (April 26, 1992), the following information is submitted:

1. **Name:** Surgical Dynamics, Inc.
 Address: 2575 Stanwell Drive
 Concord, CA 94520
 Telephone: 510 687 2192 extension 509
 Contact: Charmaine Henderson
 Date of Summary Preparation: August 1995

2. **Name of Device:** Surgical Dynamics, Inc. 30K Working Channel Scope
 and Instrument Kit for Automated Laparoscopic
 Discectomy

 Generic Name: Rigid Endoscope and Instrument Set

3. **Predicate device:**

 Surgical Dynamics 30K Working Channel Scope for Automated
 Percutaneous Lumbar Discectomy

 Argus Medical Company Laparoscopic Discectomy Instrument System

 Nucleotome System and Probe Kits

4. **Device Description:**

 The Surgical Dynamics 30K Working Channel Scope and Instrument Kit for
 Laparoscopic Discectomy are comprised of the following components:

 30K Working Channel Scope
 Nucleotome 2.5 mm Laparoscopic Probe
 Nucleotome 3.5 mm Laparoscopic Probe
 Nucleotome 4.7 mm Laparoscopic Probe
 IA Cannula
 Grasping Forceps with Teeth for Laparoscopic Discectomy

The Nucleotome probes are used in conjunction with the Nucleotome console.

5. **Intended Use:**

The intended use of the Surgical Dynamics Working Channel Scope for Automated Laparoscopic Discectomy is to decompress a herniated lumbar disc using direct

visualization during a laparoscopic procedure.

6. Technological Characteristics of the Device:

The Surgical Dynamics Working Channel Scope for Automated Laparoscopic Discectomy is identical in design, materials and energy source as the predicate device, the Surgical Dynamics 30K Working Channel Scope for Automated Percutaneous Lumbar Discectomy. The intended use is the same as the predicate device; Argus Medical Company Laparoscopic Discectomy Instrument System. The Surgical Dynamics 2.5 mm Laparoscopic Probe, Surgical Dynamics 3.5 mm Laparoscopic Probe and the Surgical Dynamics 4.7 mm Laparoscopic Probe are identical in design, materials and energy source to the predicate Surgical Dynamics probes and kits with one exception; the new devices are longer in length.